

REMARKS

I. Status of the Claims

Claims 1-21 are pending. Claims 20 and 21 are withdrawn. Applicants have amended claims 1-6 to recite specific hybridization conditions. Support for these amendments can be found in paragraph [0017] of the specification. Applicants have amended claims 3-6 by deleting “hybridizing” and inserting “that hybridizes” so that the language of claims 3-6 parallels that of claims 1 and 2. Applicants have also amended claim 8 to correct a minor typographical error. These amendments do not add new matter.

II. The Claims Satisfy the Written Description Requirement

The Examiner rejects claims 1-19 under 35 U.S.C. § 112, first paragraph, for alleged failure to satisfy the written description requirement. Office Action, pp. 8-9. According to the Examiner, “the instant specification does not have support for the limitation, ‘provided that said polynucleotide does not comprise nucleotides 2053 to 2074 of SEQ ID NO: 2.’” *Id.* at 9.

Applicants respectfully traverse. “[L]ack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support.” *Id.* (quoting *Ex parte Parks*, 30 U.S.P.Q.2d 1234, 1236 (Bd. Pat. App. & Inter. 1993)). In *Parks*, the patent application taught reactions in which no catalyst was used, but did not specifically state that the reaction was free of catalyst. *Id.* at 1236. The Examiner rejected claims that specifically recited reactions “being conducted in the absence of catalyst.” *Id.* at 1235. The Board reversed because the description described several reactions lacking a catalyst because “[t]hroughout the

discussion which would seem to cry out for a catalyst if one were used, no mention is made of a catalyst.” *Id.* 1236.

The instant application is quite similar to that of *Parks*. The specification discloses that the 5' end of the CARP sequence can be deleted without losing *in vivo* activity. See Specification, paragraph [030]. Just as in *Parks*, the specification provides numerous examples that support the negative limitation—sequences that do not comprise nucleotides 2053 to 2074 of SEQ ID NO: 2—and evidence that these sequences exhibit the claimed property appears throughout the specification. See, e.g., Examples 2, and 8-12.

In the Office Action mailed October 16, 2006, the Examiner asserted that the sequence disclosed in GenBank Accession No. AF131884 (“Aihara”) aligns with SEQ ID NO: 3 of this application. Office Action, mailed October 16, 2006, p. 16. The Aihara sequence is SEQ ID NO: 2. Specification, paragraph [024]. The Office Action mailed October 16, 2006, provided an alignment produced using the BLAST algorithm. That alignment shows that SEQ ID NO: 3 does not comprise nucleotides 2052 to 2074 of SEQ ID NO: 2. Thus, Applicants’ specification provides literal support for polynucleotides that do not comprise nucleotides 2053 to 2074 of SEQ ID NO: 2. Such alignment of sequences is routine in the art, and would reveal that none of the claimed sequences comprise these nucleotides. Thus, support for the claimed polynucleotides is also inherent in the specification.

Applicants respectfully submit that the specification as-filed fully supports the claimed nucleotides that do not comprise nucleotides 2053 to 2074 of SEQ ID NO: 2, and request that the Examiner withdraw the rejection.

III. The Claims Are Not Anticipated

The Examiner rejects claims 1-6, 15, and 17-19 under 35 U.S.C. § 102(b) as allegedly anticipated by WO99/65924 ("the '924 application"). Office Action, p. 10. The Examiner asserts that "one of the polynucleotides of the '924 invention is fully complementary to nucleotides 752-761 of SEQ ID NO: 7 of the instant invention and thus will hybridize with either of SEQ ID NOs: 3-7 of the instant invention." *Id.* at 11. The Examiner states that additional sequences in the '924 application are identical over different regions spanning ten nucleotides that would allegedly hybridize under stringent conditions as defined in Maniatis *et al.*, Molecular Cloning, A Laboratory Manual, Cold Spring Harbor 1982. ("Maniatis") *Id.* at 11-12. The Examiner also submits that the '924 application discloses a gene delivery vehicle and pharmaceutically acceptable carriers. *Id.* at 10.

Applicants traverse. The sequences of the '924 application do not anticipate the claimed sequences. The sequences that are allegedly identical to the claimed sequences are only identical over a ten base pair region. Accordingly, the full-length sequences of the '924 application do not anticipate because they do not disclose all the elements of the claims. See MPEP § 2131 (8th ed., 5th rev. 2007).

The sequences of the '924 application fail to anticipate the claimed polynucleotides at least because the prior art sequences do not possess the claimed function. Claim 1 recites polynucleotides which, in the absence of inverted terminal repeat sequences from adeno-associated virus, specifically induce expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide. Nothing in the '924 application suggests that the ten base pair sequence of the '924 application

can support the recited function. Accordingly, the '924 application does not expressly or inherently disclose all the elements of the claims.

The sequences of the '924 application also fail to anticipate the claims because they would not hybridize under high stringency conditions as alleged by the Examiner. Applicants have amended claim 1 to recite specific high stringency conditions. Applicants respectfully assert that a duplex of ten base pairs would not hybridize under the recited conditions because the melting temperature of such a duplex is substantially below 65 °degrees. If the Examiner is relying on a particular section of Maniatis to support its contention that a ten base pair sequence will hybridize under the recited high stringency conditions, Applicants request that the Examiner specifically point to that section.

Applicants respectfully submit that the '924 application does not anticipate claims 1-6, 15, and 17-19, and request that the Examiner withdraw the rejection.

CONCLUSION

In view of these amendments and remarks, Applicants submit that the application is in condition for allowance.

Please grant any extensions of time required to enter this paper and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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By: _____


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